REMARKS/ARGUMENTS

Applicants have studied the final Office Action dated January 27, 2009, have conducted an Interview with the Examiner, and have made amendments to the claims. It is submitted that the application, **as amended**, is in condition for allowance. By virtue of this **amendment**, claims 1 to 97 remain in the application. Claims 1 to 6, 10 to 21, 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 are subject to examination. **Claims 1, 15, 16, 20, and 25 have been amended.** Claims 7 to 9, 22, 23, 30 to 39, 61 to 64, 68, 69, 73, 74, 78, 79, 83, 84, 88, 89, 93, 94, 98 to 109 have been withdrawn from examination.

Reconsideration and allowance of the pending claims in view of the above amendments and the following remarks is respectfully requested.

In the Office Action, the Examiner:

I. (Pg. 2) rejected claims 1 to 4, 10, 11, 40, 47, and 65 to 67 under 35 U.S.C. § **102(b)** as being fully anticipated by U.S. Patent No. 6,319,278 to Quinn;

II. (Pgs. 2-3) rejected claims 1 to 4, 6, 10, 14, 15, 18, 19, 40, 41, 43, 47, 49, 53, 65 to 67, 70 to 72, and 80 to 82 under 35 U.S.C. § **102(b)** as being fully anticipated by International Patent Publication No. WO 99/37242 to Philips et al. (hereinafter "Philips");

III. (Pg. 3-4) rejected claims 25 to 29, 45, 46, 57, 59, 90 to 92, and 95 to 97 under 35 U.S.C. § **102(b)** as being fully anticipated by U.S. Patent Publication No. 2003/88305 to Van Schie et al. (hereinafter "Van Schie");

IV. (Pgs. 4-5) rejected claims 5, 12, 13, 16, 17, and 42 under 35 U.S.C. § **103(a)** as being unpatentable over Philips in view of U.S. Patent No. 6,821,291 to Bolea et al. (hereinafter "Bolea");

V. (Pg. 5) rejected claims 16, 17, 51, and 75 to 77 under 35 U.S.C. § **103(a)** as being unpatentable over Van Schie in view of Bolea;

VI. (Pg. 5) rejected claim 48 under 35 U.S.C. § **103(a)** as being unpatentable over Quinn in view of U.S. Patent No. 6,346,118 to Baker et al. (hereinafter "Baker");

VII. (Pgs. 5-6) rejected claims 48, 50, and 54 under 35 U.S.C. § **103(a)** as being unpatentable over Philips in view of Baker;

VIII. (Pg. 6) rejected claims 58 and 60 under 35 U.S.C. § **103(a)** as being unpatentable over Van Schie in view of Baker;

IX. (Pgs. 6-7) rejected claim 52 under 35 U.S.C. § **103(a)** as being unpatentable over Van Schie in view of Bolea;

X. (Pgs. 7-8) rejected claims 18 to 21, 24 to 29, 44, 53, 57, 59, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 under 35 U.S.C. § **103(a)** as being unpatentable over U.S. Patent No. 6,099,558 to White et al. (hereinafter "White") in view of U.S. Patent No. 6,464,719 to Jayaraman;

XI. (Pgs. 8-9) rejected claim 48 under 35 U.S.C. § **103(a)** as being unpatentable over Quinn in view of U.S. Patent No. 6,346,118 to Baker et al. (hereinafter "Baker");[1] and

XII. (Pg. 9) rejected claims 54, 56, 58, and 60 under 35 U.S.C. § **103(a)** as being unpatentable over White in view of Jayaraman and further in view of Baker.[2]

I. (Pg. 2) Rejection under 35 U.S.C. § 102(b) Quinn

As noted above, the Examiner rejected claims 1 to 4, 10, 11, 40, 47, and 65 to 67 under 35 U.S.C. § 102(b) as being fully anticipated by Quinn. Reconsideration of the application is requested.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (emphasis added by appellants); *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.") (Emphasis added.). According to the single source rule, all the claim's limitations must be contained in a single reference, *see, e.g., Brown v. 3M*, 265 F.3d 1349, 1351 (Fed.Cir.2001), and the reference "must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such

[1] It is noted that this rejection is an exact duplicate of the rejection on page 5 (Item VI). Therefore, it will be treated as the same rejection herein and responded to only once.

[2] It is noted that all other rejections of the claims in the non-final Office action have been withdrawn by the Examiner in this final Office action.

existence would be recognized by persons of ordinary skill in the field of the invention." *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed.Cir.2002). Thus, if only one of the elements is not shown by the cited prior art reference, then the Section 102 rejection fails.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 1, as amended, calls for a vascular repair device, including:

> a curved, metallic, longitudinal support member:
>
> > having a graft body centerline parallel to a longitudinal axis of the graft body; and
> >
> > when viewed in an orientation where the longitudinal axis and the centerline are aligned with one another, the support member is reverse-mirror symmetrical with respect to that longitudinal axis.

Simply stated, the support member of claim 1 is (1) connected to the graft body and is (2) reverse-mirror symmetrical in a particular viewed orientation.

It is believed that claim 1 was patentable over Quinn in its original form because Quinn does not have the "reverse-mirror symmetrical" feature of the "curved, metallic, longitudinal support member" of claim 1. This is true for a number of reasons. Initially, it is noted that the only place in Quinn that allegedly evidences a "curved" support member is the struts 47 and 48 in FIG. 4. Nowhere in the text of Quinn is there even a hint that the struts 47 and/or 48 are curved. The word "curve" is never used except for "recurved" in col. 2, line 27 (not applicable to the struts but to the apices). "Bent" is used once in col. 2, line 23, but, again, only with regard to the Z-stent. "Bend" is not used at all and "Bending" is only used in col. 2, line 36. This instance only relates to how the strut 47, 48 is connected at its end(s) to the Z-stent(s). "Straight" on the other hand is used many times and struts in all of the other figures and specification are shown as straight rods.

Applicants submit, therefore, that the curves of the struts 47, 48 only appear in FIG. 4 because the *draftsperson* needed to illustrate that the straight rod (47, 48) traversing from a proximal opening having a large diameter to a distal opening having a much smaller diameter. Those

having ordinary skill in the art know and those who are draftspersons know that the apices of the two Z-stents will not align on a two-dimensional page of the drawings when the two diameters are different but know that the strut 47 48 will be straight when on an actual bifurcated stent graft as the one shown in FIG. 4 of Quinn. Quinn shows and discloses the ends of the struts 47, 48 as being attached to outer apices of each Z-stent 42, 44. See col. 2, lines 32 to 34. As such, the draftsperson must show this traversal and, to do so, must curve the line – in other words, the supposed "curve" of each of the struts 47, 48 is not a physical curve in the final form of the stent graft, rather, they are drafting illusions that need to be included to illustrate that the rod 47, 48 traverses from one larger diameter Z-stent to another smaller diameter Z-stent.

As set forth in the specification of the instant application, reverse-mirror symmetrical means that a portion of the longitudinal support member 40 between a first longitudinal line (dashed line 41 in FIG. 1) and the center line 45 is a mirror image of the opposite portion of the longitudinal support member 40 between the second longitudinal line (dashed line 43 in FIG. 1) and the center line 45 but rotated 180 degrees around an axis orthogonal to the center line 45. Simply put, if the member 40 was to be cut in half at the center line 45, then the **two pieces would be alike**.

This, however, cannot occur in the embodiment shown in FIG. 4 of Quinn. It is axiomatic that a bifurcated cylindrical structure having a large proximal opening opposing two cylindrical structures each having smaller distal openings have differently curved outer circumferences. This means that any structure (e.g., the struts 47, 48) that would extend from the outermost end of the larger opening to the outermost end of one of the two smaller openings would traverse two different circumferences or, at a minimum, a substantially changing circumference from one end of the bifurcated graft to the other (42 to 44). Put another way, the two different sized openings 42, 44 have different planes-of-bending for each strut 47, 48. As such, the proximal curve of one end of the strut 47, 48 ***is different from*** the distal curve of the opposing end of the strut 47, 48. This, by definition, means that the two opposite halves of the strut 47, 48 **will not be similar**, a feature that required for being "reverse-mirror symmetrical."

Because Quinn does not and cannot disclose reverse-mirror symmetry, it cannot be said to anticipate the features of claim 1.

In the rejection, the Examiner states that "the language of the claim which recites the 'support member . . . substantially reverse-mirror symmetrical with respect to the longitudinal axis' [uses] 'substantially' [as] terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. Thus, the support member of Quinn can be 'substantially' reverse-mirror symmetrical."

Applicants disagree with this characterization. Nonetheless, in order to alleviate the Examiner's concerns regarding this feature, Applicants have amended claim 1 to remove the word "substantially" from this feature. As such, the rejection is now moot.

Claim 1 also provides that the "curved, metallic, longitudinal support member [is] connected to said graft body."

Quinn discloses a cylindrical stent graft in FIGS. 1 to 3 and a bifurcated stent graft in FIGS. 4, 5, and 8. In contrast to the claimed feature, the strut members 46, 47, 48, 52 are not connected to the graft body in any way. Instead, as set forth at col. 2, lines 32 to 35: "Struts 20, 21, and 22 extend between first and second stents 12 and 14, as shown. Struts 20-22 are constructed of fine gauge stainless steel spring wire or nitinol having a diameter of about 0.3 to 0.6 mm. Struts 20-22 **are attached to stents 12 and 14 in any suitable manner, such as soldering to outer elbows 18 at solder joint 24; they may, alternatively be attached by bending, or cut from a single piece of metal.**" Emphasis added by applicants. Never does Quinn disclose, describe, or suggest attaching any of the struts to the graft tube 31 or graft material 61. Because Quinn does not have this required element, it cannot anticipate claim 1 of the instant application.

Finally, claim 1 requires that the centerline of the support member be aligned with the central longitudinal axis of the graft body. The bifurcated stent graft of FIGS. 4 and 5 of Quinn cannot have a central longitudinal axis because is it not cylindrically symmetrical. Therefore, the stents 47, 48 cannot be viewed along a non-existent central longitudinal axis to equate to the required

feature of claim 1. Thus, for this reason, Quinn cannot be said to anticipate the features of claim 1.

Clearly, Quinn does not show a vascular repair device as recited in claim 1 of the instant application.

It is accordingly believed to be clear that no reference shows or suggests the features of claim 1. Claim 1 is, therefore, believed to be patentable over the art. The rejected dependent claims are believed to be patentable as well because they all are ultimately dependent on claim 1.

II. (Pgs. 2-3) Rejection under 35 U.S.C. § 102(b) Philips

As noted above, the Examiner rejected claims 1 to 4, 6, 10, 14, 15, 18, 19, 40, 41, 43, 47, 49, 53, 65 to 67, 70 to 72, and 80 to 82 under 35 U.S.C. § 102(b) as being fully anticipated by Philips. Reconsideration of the application is requested.

This rejection includes independent claims 1, 15, and 18. Each will be addressed in turn.

With regard to claim 1, all of the arguments set forth in Section I above are incorporated by reference herein in their entirety and are not repeated for clarity purposes. Philips does not have or suggest a curved, metallic, longitudinal support member that is reverse-mirror symmetrical with respect to a centerline parallel to the longitudinal axis of a graft body. Therefore, Philips cannot anticipate claim 1. Insofar as the only rejections of claim 1 were based upon Philips and Quinn above, claim 1 is allowable.

With regard to claim 15, the arguments set forth in Section I above are incorporated by reference herein in their entirety and are not repeated for clarity purposes. Claim 15 has been amended for the same reason as set forth above -- to eliminate the Examiner's concerns regarding the word "substantially." Philips does not have or suggest a curved, metallic, longitudinal support member that is reverse-mirror symmetrical with respect to a centerline parallel to the longitudinal axis of a graft body. Therefore, Philips cannot anticipate claim 15. Insofar as the only rejection of claim 15 was based upon Philips, claim 15 is allowable.

With regard to both claims 1 and 15, the structural framework of the claimed stent graft must have at least two **Z-stents**. Z-stents are well-defined in the art and also are defined in the specification. Page 2 of the specification cites U.S. Patent No. 5,282,824 to Gianturco as describing "a zig-zag-shaped, self-expanding stent commonly referred to as a z-stent." A plethora of articles written by individuals in the art interchangeably refer to a "Z-stent" and a "Gianturco stent." The term "Z-stent," therefore, has a particular meaning in the art of stents and stent grafts.

This meaning is absolute with regard to differentiating the Philips type of stent graft from a stent graft using Z-stents. Philips' singular wire, traversing all over the graft body, is in no way analogous to the Z-stent of claims 1 or 15. In particular, the Philips stent graft is fabricated from a flexible sheet of graft material (rectangular or trapezoidal shaped) that is laid flat while a single sinusoidal reinforcing wire is sewn thereto. See Philips at page 22, lines 1-5. After securing the one wire, the two lateral sides of the graft material are fastened to one another to form the tubular stent graft. In such an orientation, the lateral end loops of the sinusoidal wire are interdigitated as shown in FIG. 6a or touch one another at the longitudinal suture line of the graft body as shown in FIG. 6b. This single wire is present in every orientation of Philips and is required to carry out the function intended by the Philips inventors. On pages 3 and 12, this feature is clearly indicated: "the reinforcement elements extending annularly around the tube"; and "sinuous arrangement where opposed bends are overlapped and interdigitated . . can assist in imparting columnar strength to the tubular body."

Simply put, the kind of stent graft described by Philips is in no way related to the multiple Z-stent containing stent graft of claims 1 and 15. Thus, for these reasons as well, Philips cannot anticipate the vascular repair device of claims 1 and 15 of the instant application.

Claim 18 does not have the reverse-mirror symmetrical feature and, instead, calls for a vascular repair device, including:

> a structural framework having at least two stents each respectively connected to the tubular graft body adjacent the proximal and distal ends and defining a separation distance therebetween; and

> a longitudinal support member shorter than the separation distance and being connected to the graft body between the at least two stents to form a gimbal at at least one of the proximal and distal ends of the graft body.

In other words:

> the structural framework has two pairs of stents each respectively connected to the proximal and distal ends thereof, these two pairs of stents defining a separation distance therebetween; and
>
> the "longitudinal support member" is shorter than this separation distance and is connected to the graft body between the pairs of stents to, thereby, form a gimbal at one of the proximal and distal ends.

This means that the longitudinal support member needs to be absent somewhere between a pair of stents. In order to form a "gimbal" as set forth in this claim, the graft body has a cylindrical portion that is free from any support structure. See, for example, the circumferential cylindrical space of the graft body 10 along dashed lines 52 and 52' in FIG. 1 of the instant application. By having such a space, a portion of the stent graft on at least one side of the space (proximal of line 52 and distal of line 52') are allowed to move as the gimbal. See pages 35 et seq. of the specification of the instant application.

As discussed in the Interview, any part of the single wire traversing all over the graft material of the Philips **is not** "shorter than the separation distance" between stents connected at the opposing ends of a stent graft to form a gimbal. In fact, each portion of the single wire traversing the longitudinal extent (i.e., top-to-bottom of FIG. 12) is longer than the separation distance between any two end-most zig-zag structures (which are not Z-stents or Gianturco stents as used in the art) on the flattened graft sheet of FIG. 12. More specifically, the pillar 3 of spring element M is integral to the uppermost zig-zag structure of FIG. 12 and extends all the way to and is integral with the lowermost zig-zag structure M. This means that there exists no circumferential gaps between any two zig-zag structures on the Philips device that could possibly create the gimbal required in claim 18.

With regard to claim 18, on page 3 of the Office action, the following argument is proffered by the Examiner: "since there are end stents **M** and the wire support member does not extend the entire distance between these ends stents, the stent graft forms a gimbal at an end." This conclusion, however, cannot be true. After a thorough examination of each of the twenty-eight (28) pages of drawings and of the specification, Philips reveals that it does not disclose any embodiment where the "wire support member does not extend the entire distance between these ends" structures M as alleged in the rejection of claim 18. Even the part 44 shown in FIG. 5 of Philips has a vertical portion of the wire 32 extending between the section 46 of low-density pitch and the section 42 of high-density pitch. While section 40 does not have *transverse* portions of the wire 32, it does have *vertical* (i.e., longitudinal) portions of the wire 32. Therefore, this section 44 cannot be considered "free" from the support wire 32 as argued. It is true that the region 306 in FIGS. 24a and 24b is not covered by graft material 300, 308. Nonetheless, this region 306 contains vertical supporting wires – at least six of them!

For all of these reasons, Philips cannot anticipate claim 18. Insofar as the only Section 102 rejection of claim 18 was based upon Philips (see Section X below), claim 18 is believed to be patentable over the art.

Claims ultimately dependent on any of claims 1, 15, or 18 are believed to be patentable as well due to their respective dependencies.

III. (Pgs. 3-4) Rejection under 35 U.S.C. § 102(b) Van Schie

As noted above, the Examiner rejected claims 25 to 29, 45, 46, 57, 59, 90 to 92, and 95 to 97 under 35 U.S.C. § 102(b) as being fully anticipated by Van Schie. Reconsideration of the application is requested.

This rejection includes independent claims 25 and 28. Each will be addressed below.

As will be explained below, it is believed that claims 25 and 28 are patentable over the cited art in their current form and, therefore, these claims have not been amended to overcome Van Schie. Before discussing Van Schie in detail, it is believed that a brief review of the invention as

claimed, would be helpful. Claim 25, as presently existing, calls for a vascular repair device, including, in relevant part:

> a structural framework having at least two pairs of stents each respectively connected to the graft body adjacent the proximal and said distal end, the stents of each of pair separated from one another to define respective outer and inner stents; and
>
> a curved longitudinal **support member**:
>
> having a portion between its two ends **curved partially around the circumference of a tubular graft body**; and
>
> being **connected to the graft body between both of the inner stents such that longitudinal contraction of the graft body is substantially prevented where the support member is connected to the graft body**.

Claim 28, as presently existing, calls for a vascular repair device, including, in relevant part:

> a structural framework having at least three stents, two being connected to a tubular graft body adjacent a first end and being separated from one another on the graft body to define an outer and an inner stent, the third being connected to the tubular graft body adjacent a second end; and
>
> a longitudinal **support member** having two ends and **being connected to the graft body between the inner stent and the third stent without touching the inner and third stents such that longitudinal contraction of the graft body is substantially prevented where the support member is connected to the graft body**.

As explained in the specification, the support member that is set forth in claims 25 and 28 is one that, as it is named, *provides support to* the graft body. Graft bodies of stent grafts are formed of a material that does not stretch under normal use, but that can be compressed. Such material properties are shown, for example, in the figures of Van Schie at FIGS. 2, 4, 6, 8, 10, and 14. **Van Schie discloses that compression is a desirable and important trait** to its invention and that the inventive "length reduction arrangement" 8 is, by its own name, ***intended to compress*** longitudinally, the Van Schie graft body. See, e.g., paragraphs [0023],

This disclosed requisite feature of Van Schie is *exactly the opposite* of the support that the "support member" of claims 25 and 28 provides. More specifically, where the support member

of the claims is attached to the graft body, the support member ***prevents longitudinal compression***! By preventing longitudinal compression, the graft does not collapse or lose length.

The Examiner indicated, in the recent interview, that presenting this feature within claims 25 and 28 would be beneficial towards overcoming the rejection of Van Schie. Accordingly, Applicants have amended these claims to even more clearly define what support the support member provides. In particular, the connection between the graft body and the longitudinal support member has been changed to substantially prevent "longitudinal contraction of the graft body . . . where the support member is connected to the graft body."

As Van Schie does not disclose or suggest prevention of longitudinal contraction – in fact, it requires the opposite – it cannot anticipate claims 25 and 28.

There are other reasons that make this conclusion axiomatic. First, the properties of Van Schie's length reduction arrangement 8 are entirely different from the support member of claims 25 and 28. This arrangement is first described as an "elastic material 8," which cannot be compared to the support member of claim 25. In paragraph [0045], the "length reduction arrangement" 8 is said to be of an elastomer or of a shape memory metal. The elastomer is, by definition and by express disclosure, elastic. Thus, it cannot prevent longitudinal contraction. As for a shape memory metal, Van Schie does not mention this embodiment anywhere other than in paragraphs [0023] or [0024], the former providing: "This may for instance be a longitudinally extending zig zag or z stent which has been stretched to be substantially straight for deployment but resumes its zig zag nature and hence reduces in length during release from deployment." Paragraph [0024] mentions that the metallic length reduction arrangement can be a "stainless steel spring."

The Examiner immediately agreed with Applicants in the Interview that the ***only*** way a shape memory metal, such as nitinol, could be used to accomplish the function described in Van Schie is if that metal was formed as a device having a spring constant -- e.g., as a coil or a zig-zagged rod. As shown in FIGS. 1 and 2 (reproduced below) and disclosed in paragraph [0023], the stent graft of Van Schie **must** be able to stretch into the longitudinally straight configuration shown in

FIG. 1 to make possible loading of the stent graft into a delivery system. If a metallic version of the length reduction arrangement 8 *permits* longitudinal expansion, then it cannot be said to disclose or suggest *prevention of* longitudinal contraction/compression.

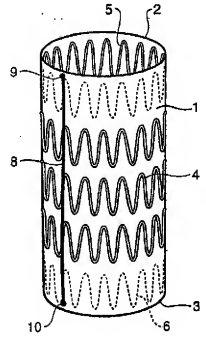


Fig 1

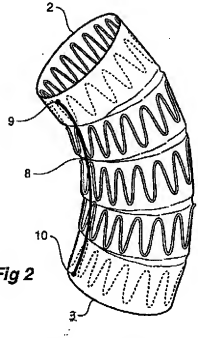


Fig 2

Further, if the shape memory metal was a straight inelastic rod, a configuration that looked just like FIG. 2 would never be able to be changed to the configuration of FIG.1. This would cause significant problems if the length reduction arrangement was not radially aligned with the inferior curve of the vessel because a kink would occur.

Second, claim 25 requires a portion of the support member to traverse *around the circumference* of the tubular graft body. As a length reduction device, it is logical that the arrangement 8 is always depicted in Van Schie as a straight line extending from a first anchor point 9 to a second anchor point 10. The length needs to be reduced in the pre-defined way (compare FIGS. 1 and 2) to approximate the desired curve of FIG. 2. This is accomplished and disclosed in Van Schie by always using and disclosing a length reduction arrangement that is straight. Any variation of this straight line would twist the stent graft in a way that does not conform to anatomy. Simply put, there is no curved support member disclosed in Van Schie. The only "curve" mentioned with

regard to the length reduction arrangement 8 is the bend of the graft body illustrated in FIG. 2 of Van Schie. See above. This "curve," however, exists only in the innermost anterior straight line of the graft tube 1, which tube has a circumference *orthogonal to* this straight line. This means that the curved member 8 does not, cannot, and is not suggested to *extend laterally around any portion of a circumference* of the graft tube 1. Without a circumferential traverse, Van Schie cannot anticipate the features of claim 25.

The only other rejection of claims 25 and 28 is set forth in Section X below. With the overcoming of such rejections too, it is believed that no reference shows or suggests the features of either claim 25 or claim 28. Claims 25 and 28 are, therefore, believed to be patentable over the art. Claims ultimately dependent on claims 25 or 28 are believed to be patentable as well due to this dependency.

IV. (Pgs. 4-5) Rejection under 35 U.S.C. § 103(a) Philips and Bolea

As noted above, the Examiner rejected claims 5, 12, 13, 16, 17, and 42 under 35 U.S.C. § 103(a) as being unpatentable over Philips in view of Bolea. Reconsideration of the application is requested.

In section II above, applicants detailed the reasons why Philips did not relate to the features of instant invention. These arguments are equally applicable herein with regard to independent claim 16 and are, therefore, incorporated herein by reference. In summary, Philips discloses a singular wire, traversing all over the graft body, that is in no way analogous to the Z-stent requirement of claim 16. The Philips stent graft is fabricated from a flexible sheet of graft material (rectangular or trapezoidal shaped) that is laid flat while a **single sinusoidal reinforcing wire** is sewn thereto. See Philips at page 22, lines 1 to 5. After securing the one wire, the two lateral sides of the graft material are fastened to one another to form the tubular stent graft. The kind of stent graft described by Philips is entirely different from the multiple Z-stent-structural stent graft of claim 16.

Claim 16 calls for, in relevant part, a vascular repair device, including:

> a structural framework having at least two Z-stents connected circumferentially to a tubular graft body; and
>
> a longitudinal support member connected to said graft body independent of said structural framework and having two ends, at least one of said ends having a longitudinal extremity curved back upon itself.

Another required feature of claim 16 is that the longitudinal support member must be "independent of" the structure framework of Z-stents. If Philips does not have, disclose, or suggest Z-stents, then it cannot be anticipating. Moreover, any part of the single wire that could be considered as a "longitudinal support member" (an argument that Applicants cannot admit) is not *independent of* the rest of the structural framework, rather, it is *integral with* the structure framework. Thus, it cannot anticipate claim 16.

In this combination rejection, the Examiner admits that "Philips fails to disclose the longitudinal member has looped ends at the extremities." In an attempt to overcome this deficiency, Bolea is combined because it allegedly teaches "(Fig. 22) a stent with a wire member having looped extremities 184." But, even if this argument could be accepted (which Applicants do not), Bolea does not overcome the deficiency of having the independent longitudinal support member. Thus, the combination cannot suggest claim 16. Significantly, the looped extremities 184 of Bolea are found on the end of **mesh**-structured stent -- a stent that, by definition, has no independent longitudinal support members because they are all interwoven. Thus, any teach of a looped-end to a mesh stent would not send one skilled in the art towards the features of claim 16, rather, it would send that person towards a feature that could be used to collapse the stent graft -- because the Bolea loops "so long as the ... element is designed so as to be capable of collapsing an end of a stent." Col. 10, lines 31 to 36.

FIG. 22 of Bolea clearly shows that these loops 184 are formed at longitudinal ends of **multi-wire braided** stents having "a mesh structure." Bolea at col. 4, line 40; see also FIGS. 1, 2, 5, 7, 8, 10, 11, 12, 14, 15, 16, 18, 19, 20, 21, 22, and 23. In its proper context, Bolea teaches placement of loops at the extreme ends of a "collapsing element [formed as] a discontinuous spiral 180." This element assists in collapsing of the tubular graft. Thus, instead of placing the loops on a structure that *provides* longitudinal support, the loops 184 are placed on a device that

removes longitudinal support!!! Simply put, Bolea teaches application of the loops to ends of something that teaches a function entirely at odds with the "longitudinal support member" of claim 16.

Because Philips and Bolea both do not relate to Z-stent stent grafts, this looped-end teaching simply is not relevant to the Z-stent art that is applicable to the instant invention. In fact, it teaches exactly in the opposite direction of claim 16.

The Supreme Court holds that "when the prior art **teaches away** from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 127 S. Ct. at 1740 (emphasis added). Here, the combination of Philips and Bolea teach away from inserting a collapsing element onto a single-snaked-wire stent having no Z-stents and no longitudinal support member.

If, for the sake of argument, such a combination could be accepted, then one having ordinary skill in the art would not be taught to apply the Bolea loops to a non-existent longitudinal support member of Philips. Instead, that person would be taught to apply the loops *to the only two ends of the single snaking wire 16 of Philips*!

There is only one argument that is provided with respect to completing this two-reference combination rejection. This argument is set forth in its entirety as follows:

> It would have been obvious to one of ordinary skill in the art to use looped ends on a longitudinal wire support member as taught by Bolea et al. and incorporate into the stent graft of Philips et al. to *provide the ability to remove the prosthesis if necessary.*

Final Office action at pages 4 to 5. This single, half-sentence clause to make a combination rejection is the exact kind of reasoning frowned upon by the Supreme Court. In *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (April 30, 2007), the Supreme Court states that the "analysis [of obviousness] should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the

legal conclusion of obviousness")." Here, there is no such explicit analysis, just a single conclusory statement. Thus, the burden of showing how these references can possibly suggest applying a loop to a longitudinal support member has not been met, especially where neither Philips nor Bolea actually have a longitudinal support member. Further, the Examiner is suggesting that one having ordinary skill in the art would put loops on ends of longitudinal support members to be able to remove an implanted prosthesis. Respectfully, Applicants believe that there would be no physician (able to keep his license) who would try to remove a stent graft as claimed in claim 16 using loops at the end of a longitudinal support member. This is because any such action would only serve to rip the stent graft along a vessel, not cause it to natrually self-compress as *mesh*-stents do when pulled longitudinally.

On pages 10 to 11 of the final Office action, the Examiner cites case law for the proposition that another recognized advantage of stent graft removal would flow from the Philips-Bolea hypothetical device. There simply is no recognized advantage of ripping a self-expanding stent graft along the inside of a vessel by pulling on a looped end of a longitudinal support member. As disclosed in the instant specification, unless there is some ability to re-compress the stent graft *radially within the lumen* -- which cannot be done to the hypothetical device -- there is no "advantageous" way of removal without tearing the vessel and/or killing the patient. Simply put, this argument cannot be accepted.

The Supreme Court has held that the Federal Circuit's teaching, suggestion, or motivation test is not inconsistent with the analysis set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and can be used in the "expansive and flexible approach" of determining obviousness *vel non*. *KSR*, 127 S. Ct. at 1739. See also *DyStar Textilfarben GmbH & Co. Deutschland KG. v C.H. Patrick Co.*, 464 F. 3d 1356, 1367 (Fed. Cir. 2006) (flexible approach); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006) (flexibility in obviousness jurisprudence). Applied to the circumstances here, there is no teaching, no suggestion, and no motivation to arrive at the features of the instant claims.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of

various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the applicant". *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). "Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so." *ACS Hospital Systems, Inc. v. Montefiore Hospital et al.*, 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be '**clear and particular.**'" *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). Appellant respectfully believes that there is no "clear and particular" teaching or suggestion in Philips to incorporate the features of Bolea, and there is no "clear and particular" teaching or suggestion in Bolea to incorporate the features of Philips.

In establishing a *prima facie* case of obviousness, **it is incumbent upon the Examiner** to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant's disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). The requisite reason why one of ordinary skill in the art would have been led to modify Philips with Bolea or to combine Philips' teachings with Bolea's teachings to arrive at the claimed invention has not been provided.

It is respectfully believe that the Examiner simply has failed to meet the burden for satisfying the above requirements to allow a combination rejection to stand.

It is accordingly believed to be clear that no cited reference shows or suggests the features of claim 16. Claim 16 is, therefore, believed to be patentable over the art. Claims ultimately dependent on claim 16 are believed to be patentable as well due to this dependency.

Finally, it is noted that all of the claims rejected in this section are dependent except for claim 16. Applicants respectfully believe that these dependent claims are believed to be patentable because of their ultimate dependency upon independent claims 1 and 16.

V. (Pg. 5) Rejection under 35 U.S.C. § 103(a) Van Schie and Bolea

As noted above, the Examiner rejected claims 16, 17, 51, and 75 to 77 under 35 U.S.C. § 103(a) as being unpatentable over Van Schie in view of Bolea. Reconsideration of the application is requested.

In section III above, applicants detailed the reasons why Van Schie did not relate to the features of instant invention. These arguments are equally applicable herein with regard to independent claim 16 and are, therefore, incorporated herein by reference. In section IV above, applicants detailed the reasons why Bolea did not relate to the features of instant invention and that combination of a curved end with a stent graft having z-stent structures would not provide any advantageous feature for removing that stent graft. These arguments are equally applicable herein with regard to independent claim 16 and, likewise, are incorporated herein by reference.

In summary, Van Schie discloses that the only part that can be compared to the longitudinal support member is the **elastic** length reduction arrangement. This device allows the graft to both expand and contract from the attached position shown in FIG. 2 therein. Claim 16 requires a longitudinal support member, not a longitudinal ***non-support*** member.

In this combination rejection, the Examiner admits that "Van Schie et al. fail to disclose the support member extremity is curved back on itself." In an attempt to overcome this deficiency, Bolea is combined because it teaches "(Fig. 18) that wire support members are curved back on themselves to form loops 170 to **retrieve the stent at a later time**, see entire patent for reason of loops." Final Office action at page 5 (emphasis added by Applicants). As indicated above, the

Bolea loops 170 are formed with respect to **braided** stents having "a mesh structure." Bolea at col. 4, line 40; see also FIGS. 1, 2, 5, 7, 8, 10, 11, 12, 14, 15, 16, 18, 19, 20, 21, 22, and 23. In the context of Bolea, therefore, this reference teaches placement of loops at the extreme ends of some of the wires forming the "mesh structure." *Id.* In other words, Bolea teaches application of the loops to ends of the *circumferential* supporting structure – not the *longitudinal* supporting structure -- so that longitudinal forces cause the stent to collapse. There is no way that placing Bolea's loops onto Van Schie would cause the Van Schie stent graft (e.g., non-braided) to collapse for removal. Because Bolea's teachings do not relate to Z-stent stent grafts like Van Schie, this looped-end teaching simply is not relevant to the Van Schie Z-stent stent graft art and, more particularly, creates a dangerous product if used as suggested. If, for the sake of argument, such a combination could be believed, then one having ordinary skill in the art would not be taught to apply the Bolea loops to the Van Schie elastic member 8. Instead, that person would be taught to apply the loops (such as loop 170 in FIG. 17) *to the apices of the stents 5, 6 in Van Schie and not to the longitudinal support structure 8*! But, even in that embodiment, it would not collapse the stent graft for removal.

The only argument that has been provided with respect to completing this two-reference combination rejection is set forth in its entirety as follows:

> It would have been obvious to one of ordinary skill in the art to modify the extremities of the longitudinal support member as taught by Bolea et al. in the stent graft of Van Schie et al. *such that the ability to retrieve the stent graft can be accomplished easily if the need arises in the patient.*

What the Examiner indicates as the motivation for changing the Van Schie teaching with Bolea's looped ends is "*ability to retrieve the stent graft*" but the instant patent and, especially, claim 16 does not deal with the issue of retrieving the stent graft. Instead, it deals with a Z-stent circumferential structural framework and a "longitudinal support" member having a curved back end.

This single sentence obviousness conclusion is the exact kind of reasoning frowned upon by the Supreme Court. In *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (April 30, 2007), the Supreme Court states that the "analysis [of obviousness] should be made explicit. See *In re*

Kahn, 441 F. 3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")." Here, there is no such explicit analysis, just a single conclusory statement – and a statement that is entirely unrelated to longitudinal support. Thus, the burden of showing how these references can possibly suggest using a looped backed end on a longitudinal support member has not been met.

The Supreme Court holds that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 127 S. Ct. at 1740. The Supreme Court also has stated that "the effect of demands known to the design community or present in the marketplace" can supplement background knowledge possessed by one having ordinary skill in the art. *Id.* at 1740-1741. "[I]t often may be the case that market demand, rather than scientific literature, will drive design trends." *Id.* at 1741.

The Examiner seems to be following a feature in the art that permits retrieval of stent grafts. The feature at issue in this rejection has **nothing** to do with *retrieval* of stent grafts. In complete contrast to this, desirable aspects of the features of claim 16 include, for example, prevention of a puncture danger at the extreme ends of the longitudinal support member and improvement in the securing of the support member to the stent graft. A comparison of entirely unrelated features can only lead to one conclusion -- that one having ordinary skill in the art would not be motivated in any way to address the issue solved by the invention with technology that is entirely unrelated to Z-stent stent grafts.

The Supreme Court has held that the Federal Circuit's teaching, suggestion, or motivation test is not inconsistent with the analysis set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and can be used in the "expansive and flexible approach" of determining obviousness *vel non*. *KSR*, 127 S. Ct. at 1739. See also *DyStar Textilfarben GmbH & Co. Deutschland KG. v C.H. Patrick Co.*, 464 F. 3d 1356, 1367 (Fed. Cir. 2006) (flexible approach); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006) (flexibility in obviousness jurisprudence). Applied to the circumstances here, there is no teaching, no suggestion, and no motivation to arrive at the features of the instant claims.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the applicant". *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). "Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so." *ACS Hospital Systems, Inc. v. Montefiore Hospital et al.*, 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be '**clear and particular.**'" *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). Appellant respectfully believes that there is no "clear and particular" teaching or suggestion in Van Schie to incorporate the features of Bolea, and there is no "clear and particular" teaching or suggestion in Bolea to incorporate the features of Van Schie.

In establishing a *prima facie* case of obviousness, **it is incumbent upon the Examiner** to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant's disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). The requisite reason why one of ordinary skill in the art would have been led to modify Van Schie with Bolea or to combine Van Schie's teachings with Bolea's teachings to arrive at the claimed invention has not been provided.

A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs. Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Appellant respectfully believes that any teaching, suggestion, or incentive possibly derived from the prior art is only present with hindsight judgment in view of the instant application. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the appellant's structure as a template and selecting elements from references to fill the gaps." *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). The Examiner has attempted to meet his burden with an impermissible hindsight view of the **current** state of the art, thus, the combination rejection must fail.

Failure to meet the burden for satisfying the above requirements requires removal of the combination rejection.

It is accordingly believed to be clear that no reference shows or suggests the features of claim 16. Claim 16 is, therefore, believed to be patentable over the art. The dependent claims in the rejection ultimately depend upon claim 16 and, therefore, are likewise believed to be patentable as well due to this dependency.

VI. (Pg. 5) Rejection of under 35 U.S.C. § 103(a) Quinn and Baker

As noted above, the Examiner rejected claim 48 under 35 U.S.C. § 103(a) as being unpatentable over Quinn in view of U.S. PatentNo. 6,346,118 to Baker et al. (hereinafter "Baker") Reconsideration of the application is requested.

Insofar as claim 48 is ultimately dependent upon claim 1, it is respectfully believed that this claim is allowable based upon this dependency. All arguments set forth above with regard to claim 1 are hereby incorporated by reference herein.

VII. (Pgs. 5-6) Rejection under 35 U.S.C. § 103(a) Philips and Baker

As noted above, the Examiner rejected claims 48, 50, 54 under 35 U.S.C. § 103(a) as being unpatentable over Philips in view of Baker. Reconsideration of the application is requested.

Insofar as claims 48, 50, and 54 are ultimately dependent upon claims 1, 15, or 18, it is respectfully believed that these claims are allowable based upon this dependency. All arguments set forth above with regard to claims 1, 15, and 18 are hereby incorporated by reference herein.

VIII. (Pg. 6) Rejection under 35 U.S.C. § 103(a) Van Schie and Baker

As noted above, the Examiner rejected claims 58 and 60 under 35 U.S.C. § 103(a) as being unpatentable over Van Schie in view of Baker. Reconsideration of the application is requested.

Insofar as claims 58 and 60 are ultimately dependent upon claims 25 and 28, it is respectfully believed that these claims are allowable based upon this dependency. All arguments set forth above with regard to claims 25 and 28 are hereby incorporated by reference herein.

IX. (Pg. 6-7) Rejection under 35 U.S.C. § 103(a) Van Schie and Bolea

As noted above, the Examiner rejected claims 52 under 35 U.S.C. § 103(a) as being unpatentable over Van Schie in view of Bolea. Reconsideration of the application is requested.

Insofar as claim 52 is ultimately dependent upon claim 16, and because Applicants believe claim 16 is allowable, it is respectfully believed that this claim is allowable based upon this dependency. All arguments set forth above with regard to claim 16 is hereby incorporated by reference herein.

X. (Pgs. 7-8) Rejection under 35 U.S.C. § 103(a) White and Jayaraman

As noted above, the Examiner rejected claims 18 to 21, 24 to 29, 53, 57, 59, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 under 35 U.S.C. § 103(a) as being unpatentable over White in view of Jayaraman. Reconsideration of the application is requested.

As will be explained below, it is believed that claim 18 was patentable over White and Jayaraman in its original form and that claim 20 is patentable as currently worded. Therefore, these claims have not been amended to overcome the references. Claims 25 and 28 have been amended as set forth herein but not for reasons related to either or both of White or Jayaraman.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claims 18, 20, 25, and 28 each include features where a longitudinal support member has a length smaller than a distance between two stents of the stent graft to create a gimbal on at least one end thereof. Neither Jayaraman nor White disclose or even suggest such a feature and, therefore, a combination of the two cannot suggest such a feature. The arguments with regard to the gimbal feature set forth above are hereby incorporated by reference herein to prevent redundancy. Simply put, to have a gimbal at one end of a stent graft, there is a structural framework including stents and a longitudinal support member **terminating between two independent stents** (claim 18) or **prior to a second-to-last stent of a pair of stents** (claims 20, 25, 28). Jayaraman is entirely unrelated to such independent stents (e.g., circumferential Z-stents of claim 20). Thus, it can contribute nothing towards the suggestion of claims 18, 20, 25, or 28. With regard to White, the Examiner admits that it is entirely silent on the subject of supporting members: "White et al. fail to disclose a longitudinal support member." Office Action at 6. Therefore, there is no way to support a conclusion where either White, Jayaraman, or the combination thereof can suggest any aspect of the features of claims 18, 20, 25, or 28.

In an attempt to make up for the clear deficiency of White and to complete the combination rejection, the Examiner must *add* a feature of Jayaraman to White. Specifically, the Examiner states that "Jayaraman teaches (Fig. 8) a longitudinal support member 15, 53 that is curved and

shorter than the body of the stent graft and since it is joined to the graft, it is not touching the stents." There are a number of errors with this conclusion.

First, Jayaraman teaches (1) a support member for a **mesh-type** stent (not a stent graft as in White or the claimed invention) and (2) that extends from one longitudinal end of the expandable stent all the way to the other longitudinal end. As is known to those in the art, a mesh-type stent is designed for both longitudinal expansion and longitudinal contraction. Jayaraman is no exception to that standard mesh-type stent and specifically states, at col. 2, lines 3-4 "serpentine nature of the connecting pieces allows longitudinal expansion" -- in other words these serpentine connecting pieces 15, 53 are designed to both contract and expand *longitudinally*. If these connecting pieces 15, 53 were rigid, as argued by the Examiner, then Jayaraman would no longer function. Similarly, if these longitudinally expandable and contractable connecting pieces 15, 53 were attached to the White device, then it would not provide longitudinal support to the White stent graft.

There is an inherent difference between peripheral stents (1.5 to 12 mm in diameter) and stent grafts that are like the ones in White (a bifurcated vascular stent (AAA or TAA) typically having diameters of 20-46 mm). The Jayaraman stent is very small and is formed by chemical etching. See col. 2, line 26. The mesh structure of the Jayaraman stent inherently requires length adjustment to be compressed or expanded or it will not work. If these connecting pieces 15, 53 were attempted to be used as "support" members as indicated by the Examiner, would defeat the purpose of Jayaraman's invention to allow compression to very low profile and expansion to very large diameter and they would not provide longitudinal support to the White device if they were multiplied in size to actually fit the length of the White device from one longitudinal end to the other as shown in Jayaraman. Any argument that the connecting device were hardened to provide longitudinal support to the White device simply finds no support from either disclosure. There simply is no reason why technology (longitudinal support member) for peripheral stents would be translatable to White, nor is there any motivation to connect such expanding and contracting thin wires to the support structure of White (as is required in Jayaraman).

Second, Jayaraman teaches a support member that extends from one longitudinal end of the expandable stent all the way to the other longitudinal end. Clearly shown in every Jayaraman embodiment is that the members 15, 53 either extend all the way to the ends of the mesh stent or extend virtually up to the ends. Even if one were to add Z-stents to the mesh expandable stent of Jayaraman (which applicants believe would be improper and unwarranted because it would serve no purpose for doing so and would be contrary to the mesh structure teaching of Jayaraman), there is not enough room at the ends of the mesh material 27, 35 to include such a stent so that the members 15, 53 can end prior to such a hypothetical addition thereto. In other words, Jayaraman teaches providing longitudinal support entirely from one end to the other, not shortening that support to end before at least a pair of stents on the tubular graft body. In the opposite configuration where the Jayaraman member 15, 53 are place on the White device, any such configuration would place the member 15, 53 longitudinally outside both of the outer-most stents, which means that the alleged combination could not ever provide the gimbals required in claims 18, 20, and 25!

Third, even though Jayaraman teaches attaching the members 15, 53 to its mesh tubular expandable stent, there is no teaching or even suggestion towards how those members 15, 53 would act if hypothetical circumferential stents from were attached to the mesh structure. By providing a gimbal, claims 18, 20, and 25 require that the support member extend to **not touch the stent(s) that form the gimbal**. If there is no stent on the mesh expandable tube of Jayaraman, then there is no way that this reference could ever suggest how the members 15, 53 would not touch the stents in that hypothetical situation.

But, these situations are not what is being suggested in the combination rejection. What is being argued is that the members 15, 53 of Jayaraman should be added to the White stent graft. But, if the Jayaraman members 15, 53 extend all of the way to the ends of the mesh structure there, then adding such members 15, 53 to White would mean that the members 15, 53 should extend virtually all the way to the ends of the White stent graft. This is not what is required in the rejected claims and, therefore, the rejection fails.

There is no possible suggestion in either White or Jayaraman to shorten the Jayaraman member 15, 53 to extend substantially less than that shown in every embodiment of Jayaraman. Nonetheless, this exact situation has been drafted in the hypothetical configuration shown on pages 7 and 8 of the Office action. This configuration places a hypothetical sinusoidal support member onto the White stent graft that is entirely different from the members 15, 53 disclosed by Jayaraman. Clearly, there is no disclosure or suggestion in the Office action as to why shortening should occur so that the ends of the member 15, 53 falls within the end pairs of stents on the White stent graft. What has occurred here is that, after seeing the invention of the claims, the Examiner has, with hindsight, created a desired situation in a hypothetical figure. However, this creation finds no support in either reference or in the general teachings of stent grafts to make such modifications.

A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614,1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs. Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Any teaching, suggestion, or incentive possibly derived from the cited prior art is only present with hindsight judgment in view of the present application. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. . . . The references **themselves** must provide some teaching whereby the applicant's combination would have been obvious." *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991) (emphasis added). Here, no such teaching is present in the cited references. In fact, the teaching of Jayaraman is not in a direction *towards* the suggested combination. Rather, it is in the opposite direction because White is a Z-stent configuration; in such configuration, there are two or more circumferential supporting devices 17, 17a that radially support a tubular graft about its circumference. In complete contrast, Jayaraman is a tubular mesh-type stent having a cylindrical

fabric tube with multiple serpentine shaped *longitudinal* pieces that are fastened to the tube along *longitudinal lines*; they are not fastened along circumferential lines.

The Jayaraman device is a stent, it does not have stents (plural) as defined in the instant application (see page 2, lines 9 to 14, citing U.S. Patent Nos. 5,282,824 and 5,507,771) and as known and referred to in the art. In particular, Jayaraman does not have the **"at least two stents"** required by claim 18, the **"at least two pairs of stents"** required by claims 20 or 25, or the **"at least three stents"** required by claim 28. In fact, to have "at least two stents" in the Jayaraman disclosure would mean that there would have to be two entire tubular structures each having the sets of serpentine connecting pieces. Nowhere does Jayaraman disclose entirely duplicating, triplicating, or quadrupling itself.

Jayaraman does not even relate to prostheses that use stents or, especially, Z-stents; the entire Jayaraman device *is a stent*. Merely because the title of Jayaraman uses the word "stent" does not mean that it relates to the kind of technology that utilizes the plurality of circumferential Z-stents that is described in detail in the instant application. Accordingly, there can be no motivation anywhere within the Jayaraman disclosure to implement the *tubular* mesh stent technology of Jayaraman in the *Z-stent intraluminal stent graft* disclosed in White.

The Supreme Court has held that the Federal Circuit's teaching, suggestion, or motivation test is not inconsistent with the analysis set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and can be used in the "expansive and flexible approach" of determining obviousness *vel non*. *KSR*, 127 S. Ct. at 1739. See also *DyStar Textilfarben GmbH & Co. Deutschland KG. v C.H. Patrick Co.*, 464 F. 3d 1356, 1367 (Fed. Cir. 2006) (flexible approach); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006) (flexibility in obviousness jurisprudence). Applied to the circumstances here, there is no teaching, no suggestion, and no motivation to arrive at the features of the instant claims.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the applicant".

Interconnect Planning Corp. v. Feil, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). "Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so." *ACS Hospital Systems, Inc. v. Montefiore Hospital et al.*, 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be '**clear and particular.**'" *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). There is no "clear and particular" teaching or suggestion in Jayaraman to incorporate the features of White, and there is no teaching or suggestion in White to incorporate the features of Jayaraman.

In establishing a *prima facie* case of obviousness, it is **incumbent upon the Examiner** to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the applicants' disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). The only reason provided as to why one of ordinary skill in the art would have been led to modify Jayaraman or White or to combine Jayaraman's and White's teachings to arrive at the claimed vascular repair device invention is set forth as "it provides more support to the vessel walls and assist [sic] in expansion and keep the stent in its expanded form together." Office action at 7. However, White does not provide any reason why additional vessel support would be needed in its device. Nor does White provide any reason why the White stent graft needs to be kept "in its expanded form together." These reasons seem to be set forth without looking to White's desire to improve upon the design already set forth. It is known to those skilled in the art that stent grafts having longitudinal

support that is too strong will not perform well or will not perform at all and placing longitudinal wires that can concertina on the White device will not provide longitudinal support. The Examiner has provided no reason why this hypothetical combination of the members 15, 53 onto the White disclosure would not render useless the support struction of the White stent graft or just not affect the White device's performance. In fact, placing hair-sized members 15, 53 along a longitudinal span of the White stent graft will not provide any benefit at al. If such members 15, 53 were hardened, then that hypothetical configuration would make the stent graft so inflexible that it cannot traverse curved vasculature and, instead of assisting in improvement of the vessel, would destroy the vessel (if it cannot bend through the tortous paths of common vasculature). Applicants, therefore, submit that the combination will not function as White would have intended.

More specifically, the Examiner contends that the S-shaped connecting pieces 53 of Jayaraman would "provide more support to the vessel walls and assist in expansion" if added to White. This conclusion, however, is unsupported and incorrect. There would be no assistance in the expansion of the White stent graft if the connecting pieces 53 of Jayaraman were added to White. **In fact, the opposite is true** because any relatively rigid pieces attached to the graft tube of White would *prevent expansion*, not "assist in expansion" as asserted by the Examiner. If such a combination was hypothetically made, at best, there would be *no* affect on expansion and, at worst, expansion would be *hindered* by adding the rigid pieces of Jayaraman to White.

Jayaraman clearly discloses that many of the connecting pieces 53 must be disposed about the circumference of the tubular body. There is no suggestion to use only one of the connecting pieces 53 in Jayaraman in any way and, especially, there is no hint or suggestion in White to make such a drastic change in the Jayaraman device. In fact, if one were to add multiple connecting pieces 53 to White (which is what is actually disclosed by Jayaraman), the resulting hypothetical stent graft would be the same as before if the pieces 53 were hair-like as disclosed in Jayaraman or, if hardened as not disclosed by Jayaraman, would be significantly or dangerously rigid about its longitudinal axis and would, therefore, *be dangerous when traversing curved vessels and not be able to be implanted in curved vessels* – thus, totally eliminating a desirable feature of stent grafts! Such hypothetical combinations, therefore, *defeat White's intended purpose.*

The Examiner cited FIG. 8 of Jayaraman for the feature that is added to White to form the combination rejection. It is significant to note that there is nothing to show or suggest in Jayaraman that the FIG. 8 prosthesis could ever function as a stent graft or even relate to a stent graft because there is no force applied by the connecting piece 53 that could ever assist in keeping the lumen of the material fabric tube 51 open after being implanted in a vessel. As such, the combination of these two different features cannot be supported.

Clearly, the combination of Jayaraman and White do not suggest the vascular repair device as recited in any of claims 18, 20, 25, or 28 of the present application.

XI. (Pg. 9) Rejection under 35 U.S.C. § 103(a) Quinn and Baker

Same as section VI above.

XII. (Pg. 9) Rejection under 35 U.S.C. § 103(a) Jayaraman and Baker

As noted above, the Examiner rejected claims 54, 56, 58, and 60 under 35 U.S.C. § 103(a) as being unpatentable over White in view of Jayaraman and further in view of Baker. Reconsideration of the application is requested.

Insofar as claims 54, 56, 58, and 60 are ultimately dependent upon claims 18, 20, 25, and 28, and because Applicants believe that these independent claims are allowable as set forth above, it is respectfully believed that these claims are allowable based upon this dependency. All arguments set forth above with regard to claims 18, 20, 25, and 28 are hereby incorporated by reference herein.

CONCLUSION

The remaining cited references have been reviewed and are not believed to affect the patentability of the claims as amended.

In this Response, Applicants have amended certain claims. In light of the Office Action, Applicants believe these amendments serve a useful clarification purpose, and are desirable for clarification purposes, independent of patentability. Accordingly, Applicants respectfully submit that the claim amendments do not limit the range of any permissible equivalents.

Applicants acknowledge the continuing duty of candor and good faith to disclosure of information known to be material to the examination of this application. In accordance with 37 CFR §1.56, all such information is dutifully made of record. The foreseeable equivalents of any territory surrendered by amendment are limited to the territory taught by the information of record. No other territory afforded by the doctrine of equivalents is knowingly surrendered and everything else is unforeseeable at the time of this amendment by the Applicants and their attorneys.

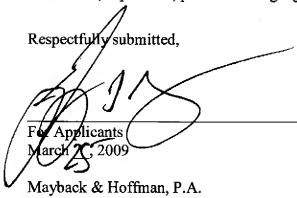
Applicants respectfully submit that all of the grounds for rejection stated in the Examiner's Office Action have been overcome, and that all claims in the application are allowable. No new matter has been added. It is believed that the application is now in condition for allowance, which allowance is respectfully requested.

If an extension of time for this paper is required, petition for extension is herewith made.

Please charge other fees that might be due with respect to Sections 1.16 and 1.17 to the Deposit Account of Mayback & Hoffman, P.A., No. 503,836.

PLEASE CALL the undersigned if discussion would expedite the prosecution of this application or in the event the Examiner should still find any of the claims to be unpatentable, in which case, if possible, patentable language can be worked out.

Respectfully submitted,



For Applicants
March 25, 2009

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